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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,798	10/12/2001	Ellen M. Heath	GSIM-01P-0014	7769

7590                    09/09/2003

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[REDACTED] EXAMINER

KHARE, DEVESH

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/09/2003

(Signature)

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/974,798	HEATH ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Devesh Khare	1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.  
 4a) Of the above claim(s) 1-20 and 44 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 21-43 and 45 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**Response to Election with Traverse**

Applicant's election with traverse of the method for purifying RNA from biological material using an RNA lysing solution defined by Group II (claims 21-43 and 45) in Paper No. 5 is acknowledged. The traversal is on the ground(s) that "the search and examination of the claims of Groups I and II can be made without serious burden". This is not found persuasive because the applicants claims encompass two distinct classes of methods for purifying RNA which would be burdensome to the examiner as it cannot be assumed that the modes of purification for one method of purification would be the same for another method of purification. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 and 44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 21-43 and 45 are currently pending in this application.

**35 U.S.C. 112, second paragraph rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 21-43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(1) The term "substantially" in claims 21, 32 and 45 is relative, and the recitation of same renders the claim indefinite. The terms "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention with regard to the substantially undegraded RNA.

(2) Regarding claims 21 and 45, the phrase "preferentially" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. Dependent claims drawn to preferred limitations would be more favorably considered. See MPEP § 2173.05(d).

(3) The terms "amphiphilic reagent" in claim 21 and "strong chaotropic substance" in claim 45 are relative terms, which render the claims indefinite. The terms "amphiphilic reagent" and "strong chaotropic substance" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(4) Claims 42 and 43 recite the limitation "the RNA binding solution" in claim 21. There is insufficient antecedent basis for this limitation in the claim. There is no mention of the RNA binding solution in claim 21. Either the step wherein the purification comprises a binding solution should be recited in Claim 21 or Claims 42 and 43 should be cancelled. Therefore, the claims 42 and 43 are not been further treated on the merits.

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Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

Claims 39-41 are objected to since they are dependent on the non-elected claim 20.

Accordingly, the claims 39-41 are not been further treated on the merits.

#### **Information Disclosure Statement**

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

#### **35 U.S.C. 103(a) rejection**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 21-38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroita et al. (U.S. Patent 5,990,302).**

Claims 21-38 and 45 are drawn to method for purifying undegraded RNA from biological material comprising the steps of:

mixing the biological material with an RNA lysing solution, forming a lysate, contacting lysate to an immobilized non-silica solid support, washing the solid support with an RNA wash solution and eluting the bound RNA from solid support. Additional claim limitations include the biological material selected from the group consisting of eukaryotic cells, prokaryotic cells, microbial cells, blood, bone marrow, saliva, urine, sweat, environmental samples and solid animal tissues, non-solid support selected from the groups consisting of cellulose, nylon, polyester, the RNA complexing salt is chosen from the group consisting of lithium chloride, sodium, potassium, cesium at a concentration of between 4-10 M.

Claim 45 is drawn to method for purifying undegraded RNA from biological material comprising the steps of: contacting a biological material containing RNA with a solid support pre-treated with an RNA lysing solution, washing the solid support with an RNA wash solution and then eluting the bound undegraded RNA from the solid support.

Kuroita et al. teach a method for isolating RNA from cells safely in a high purity (abstract). Kuroita et al. disclosed the isolation of RNA from a sample of cells by mixing the sample with an RNA lysing solution containing a lithium salt and a chaotropic agent, forming a lysate, contacting lysate with a nucleic acid binding carrier such as silica particles, washing the solid support with an RNA wash solution (100 mM) and eluting the bound RNA from solid support. (col. 2, lines 44-60). Kuroita et al. disclose the

nucleic acid-binding solid support selected from the group consisting of silica, cellulose, nitrocellulose, latex and hydroxyapatite in col. 3, lines 3-5, that may have a form of particle, filter, reaction container and the like (col. 5, lines 20-22). Kuroita et al. also suggest in col. 3, lines 41-50, the RNA biological sample can be , for example, serum, blood, tissue, urine, saliva, virus and bacteria or fungus. Furthermore, in col. 6, lines 41-63, Kuroita et al. disclosed mixing a biological material containing RNA with the lysing solution and a silica solid support, washing the solid support with an RNA wash solution and then eluting the bound undegraded RNA from the solid support. Kuroita et al. differ from the applicant's invention that Kuroita et al. do not provide an explicit example of the isolation of an undegraded RNA, however Kuroita et al. provide motivation to use a lysing solution and a solid support to isolate a RNA from a biological sample in a high purity. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the method for purification of RNA of Kuroita et al. to a method of using a lysing solution and a solid support to isolate a undegraded RNA from a biological sample because the art teaches a method for isolating a RNA with high purity from a sample containing a RNA by the use of a solid support and lysing solution and those skilled in the art would be motivated to obtain the RNA in high purity because isolation of RNA from a biological sample provide important information in the fields of

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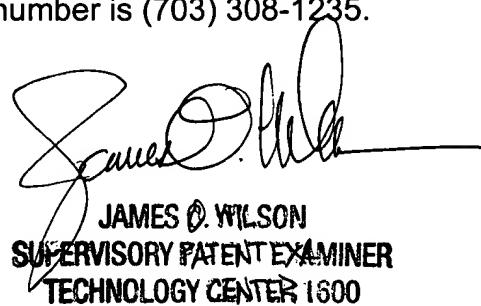
biochemistry, genetic engineering, clinical diagnostics and the like (see col.1, lines 25-29).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-

1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,JD(3Y).  
Art Unit 1623  
September 5, 2003